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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,362

10/03/2005

Nicholas D. P. Cosford

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EXAMINER

CHENG, KAREN

ART UNIT

PAPER NUMBER

1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/552,362

Applicant(s)

COSFORD ET AL.

Examiner

Karen Cheng

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 (in part), 6-8 (in part), 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☒ Claim(s) 1-6 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

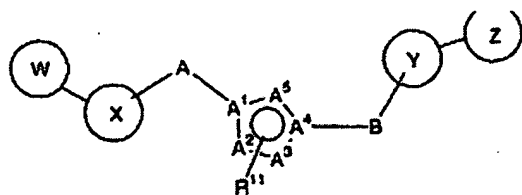
- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 10/03/05.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date 20070402.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-12 are currently pending in the instant application. Claims 9-12 are withdrawn from consideration as being drawn to non-elected subject matter

#### *Response to Election/Restrictions*

Applicant's election of a Group drawn to a compound of formula (I)

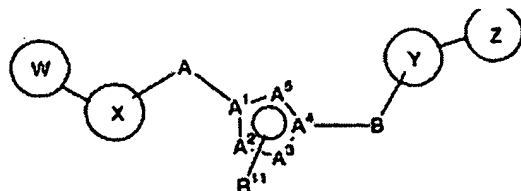


wherein A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup> and A<sup>5</sup> are defined so that the central ring is a 1,2,3-triazole, A is C<sub>0-4</sub> alkyl, B is C<sub>0-4</sub> alkyl, X is heteroaryl, Y is aryl, and the remaining variables are as defined and pharmaceutical compositions comprising said compounds filed in a response on 03/12/07 is acknowledged.

A preliminary search of this Group was made and resulted in over 8000 structure hits on the STN database. A call was made to Applicant's Representative David Rubin on April 2, 2007 to discuss further restriction because there would be a serious burden on the examiner if further restriction was not required. The Examiner and Applicant's Representative agreed that Examiner would search the invention wherein A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup> and A<sup>5</sup> are defined so that the central ring is a 1,2,3-triazole, X is a pyridine ring optionally substituted as defined, W is absent, Y is phenyl ring optionally substituted as defined, Z is a pyridine ring, A and B are C<sub>0</sub>-alkyl and the other substituents are as defined.

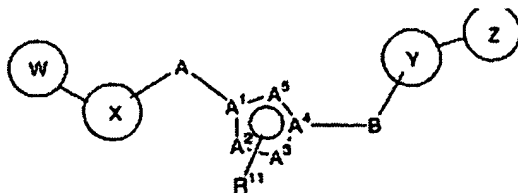
### Status of the Claims

**Claims 1-12** are pending in this application. The scope of the invention of the elected and examined subject matter is the compounds and compositions in **Claims 1-8** which share the same core structure shown below.



wherein three of A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup> and A<sup>5</sup> are N, the remaining two are C and together form a 1,2,3-triazole ring, A and B are C<sub>0</sub> alkyl, X is pyridyl, W is absent, Y is phenyl, Z is pyridyl, and R<sup>1</sup>-R<sup>11</sup> are as defined.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of **Claims 1-12** which are drawn to the core structure of



wherein three of A<sup>1</sup>, A<sup>2</sup>, A<sup>3</sup>, A<sup>4</sup> and A<sup>5</sup> are N, the remaining two are C and together form a 1,2,4-triazole ring, X is aryl or heteroaryl, except for a pyridyl ring, Y is aryl or heteroaryl except for a phenyl ring,

W is -C<sub>3-7</sub>cycloalkyl, -heteroC<sub>3-7</sub>cycloalkyl, -C<sub>0-6</sub>alkylaryl, or -C<sub>0-6</sub>alkylheteroaryl

Z is -C<sub>3-7</sub>cycloalkyl, -heteroC<sub>3-7</sub>cycloalkyl, -C<sub>0-6</sub>alkylaryl, or -C<sub>0-6</sub>alkylheteroaryl except for a pyridyl ring,

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A is  $-C_{0-4}alkyl$ ,  $-C_{0-2}alkyl-SO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-SO_2-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-CO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-NR^1CO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-NR^1SO_2-C_{0-2}alkyl-$  or  $-heteroC_{0-4}alkyl$ ;

except for  $C_0$  alkyl,

B is  $-C_{0-4}alkyl$ ,  $-C_{0-2}alkyl-SO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-SO_2-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-CO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-NR^2CO-C_{0-2}alkyl-$ ,  $-C_{0-2}alkyl-NR^2SO_2-C_{0-2}alkyl-$ , or  $-heteroC_{0-4}alkyl$ ;

except for  $C_0$  alkyl

and methods of use are withdrawn from further consideration pursuant to 37 CFR

1.142(b) as being drawn to non-elected inventions.

The scope of the invention of the non-elected and non-examined subject matter includes the compounds described in the paragraph immediately above as well as methods of use.

The withdrawn compounds contain the variety of cores, which are patentably distinct from the elected and examined core, and are chemically recognized to differ in structure, function, and reactivity. Therefore, the subject matter, which has been withdrawn from consideration as being *non-elected* subject matter materially, differs in structure and composition from the elected/examined subject matter so that a reference that anticipates the elected/examined subject matter would not render obvious the *non-elected* subject matter.

This recognized chemical diversity of the functional groups is apparent by the different fields of search required for the *non-elected* species versus the elected compounds. All compounds falling outside the search strategy of the elected compound and the structure shown above are heretofore directed to *non-elected* subject matter and are withdrawn from consideration under 35 U.S.C. § 121 and 37 C.F.R. § 1.142(b).

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It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

***Priority***

The application is a 371 of International Application No. PCT/US2004/009750, filed on 03/31/2004, which claims the benefit of priority to US Provisional Application No. 60/462,796, filed on 04/04/2003.

***Information Disclosure Statement***

Applicant's Information Disclosure Statement filed on 10/03/05 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

### ***The nature of the invention***

The nature of the invention is a composition comprising a compound of claim 1

agonist, ii) an opiate antagonist, iii) a calcium channel antagonist, iv) a 5HT receptor agonist, v) a 5HT receptor antagonist, vi) a sodium channel antagonist, vii) an NMDA receptor agonist, viii) an NMDA receptor antagonist, ix) a COX-2 selective inhibitor, x) an NK1 antagonist, xi) a non-steroidal anti-inflammatory drug, xii) a GABA-A receptor modulator, xiii) a dopamine agonist, xiv) a dopamine

and i) an opiate

antagonist, xv) a selective serotonin reuptake inhibitor, xvi) a tricyclic antidepressant drug, xvii) a norepinephrine modulator, xviii) L-DOPA, xix) buspirone, xx) a lithium salt, xxi) valproate, xxii) neuronin, xxiii) olanzapine, xxiv) a nicotinic agonist, xxv) a nicotinic antagonist, xxvi) a muscarinic agonist, xxvii) a muscarinic antagonist, xxviii) a selective serotonin and norepinephrine reuptake inhibitor (SSNR), xxix) a heroin substituting drug, xxx) disulfiram, or xxxi) acamprosate.

### ***The state of the prior art and the predictability or lack thereof in the art***

There is wide range of receptor modulators, including agonists and antagonists, and enzyme inhibitors, so it is not known what can be encompassed by this definition unless the compound is explicitly described in the instant specification. Applicants do not provide guidelines as to what assays or tests can be used to determine if a compound can be considered an enzyme inhibitor or modulator of all receptors that are listed in claim 7.

The existence of these obstacles establishes that one of ordinary skill in the art would not know what compounds can be included in the groups listed. In the instant case, the specification does not provide guidance as to how one skilled in the art would ascertain what a second compound could be. Although applicants list categories of receptor modulators, inhibitors and agents, the lack of guidelines for what specific compounds fall into these categories would fail to enable one of ordinary skill in the art to have sufficient direction to determine what the second compound in a composition could be.

***The amount of direction or guidance present and the presence or absence  
of working examples***

The specification cites several categories of receptors modulators and inhibitors on p. 15-16. However unless a compound is explicitly named, it cannot be determined what compounds can be considered to the second compound of a composition given definitions such as an opiate agonists or antagonists, etc.

***The breadth of the claims***

The instant breadth of the rejected claims is broader than the disclosure, specifically, the instant claims include a composition containing a compound from claim 1 in combination with another compound that can be an inhibitor or agonist or antagonist. Although the specification lists some known compounds that may fall into these categories, it fails to adequately provide enough direction to determine what can be considered another compound for all the inhibitor or agonist or antagonist compounds listed.



***The quantity or experimentation needed and the level of skill in the art***

It would require undue experimentation of one of ordinary skill in the art to ascertain what the second compound of the composition could be.

Factors such as "sufficient working examples", "lack of direction", etc. have been demonstrated to be sufficiently lacking in the instant case for the composition claim. In view of the breadth of the claim, the chemical nature of the invention and the lack of working examples regarding the invention as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in cope with the claim.

In consideration of the Wands factors, it is apparent that undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue. Therefore, claim 7 is rejected under 35 U.S.C. § 112, 1<sup>st</sup> paragraph.

***Claim Objections***

Claims 1 and 4 are objected to because of the following informalities: they contain subject matter that has been withdrawn from consideration. Appropriate correction is required.

Claims 2-3, 6 and 8 are objected to as being dependent upon a rejected base claim, but would appear allowable over the prior art of record if rewritten in independent form to include all of the limitations of the base claim and any intervening claims.

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Claim 5 is objected to because of the following informalities: It is improperly written. A claim that defines species within a claim should be written in the alternative form, such as "A compound according to claim 1 selected from the group consisting of" with an "and" between the last two listed compounds. There are also two periods in the claim, and there should only be one. Appropriate correction is required.

### ***Conclusion***


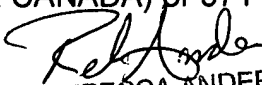
A search was made of the prior art, and the closest art was found in WIPO Pub. No. WO 03/051315 whereby similar compounds that have a heteroatom between Y = phenyl and Z = pyridyl are disclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
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